



How can we review Human Infection Challenge Studies?

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<http://www.reviewingresearch.com/human-challenge-studies/>

As with all research, it should follow the principles of good research.....



Good Research Principles: the study should:-

1. have clear, justified purpose.
2. be built on what is known already.
3. provide meaningful answers.
4. provide valid answers.
5. be conducted by researchers with appropriate expertise.
6. address a research question that is important to the field of research.
7. select participants fairly.
8. have a fair balance of benefits and harms.
9. include informed consent.
10. protect personal information.
11. include fair payments and compensation for participants.
12. be conducted in a way that respects the dignity of research participants.

We can change these very simply to make questions to frame our review....

Questions to guide review

1. Does the study have a clear, justified purpose?
2. Will it build on what is known already?
3. Will it provide meaningful answers?
4. Will it provide valid answers?
5. Is it to be conducted by researchers with appropriate skills?
6. Will it accommodate public views?
7. Will participants be selected and recruited fairly?
8. Is there fair balance of benefits and harms?
9. Will fair informed consent be sought?
10. Will personal information be protected (confidentiality)?
11. Will there be fair payments and compensation for injury?
12. Will appropriate care after research be in place?
13. Will there be a public record?

Particular issues in H.I.C.S.

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Particular issues in H.I.C.S.

Does the study have a clear, justified purpose?

- An important question/health concern, confirmed by
- independent expert review and
 - appropriate public engagement.

With an explanation as to why a challenge study is necessary (rather than less intrusive methods).

Particular issues in H.I.C.S.

Is it to be conducted by researchers with appropriate skills?

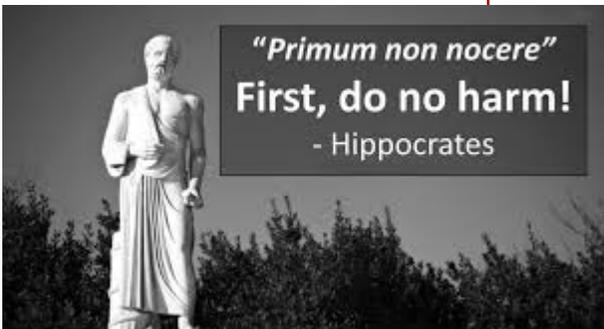
- Documented experience and training in handling and administering the infective agent.
- Specific expertise for consent processes.
- Competence in procedures, policy, national laws and regulations and requirements for trial related issues and as importantly, work under appropriate legal, institutional and professional accountability with trial monitoring in place.

Particular issues in H.I.C.S.

Will it accommodate public views?

To gain support, public involvement FROM THE BEGINNING should be encouraged.

Of particular importance in HICS given their controversial nature



Particular issues in H.I.C.S.

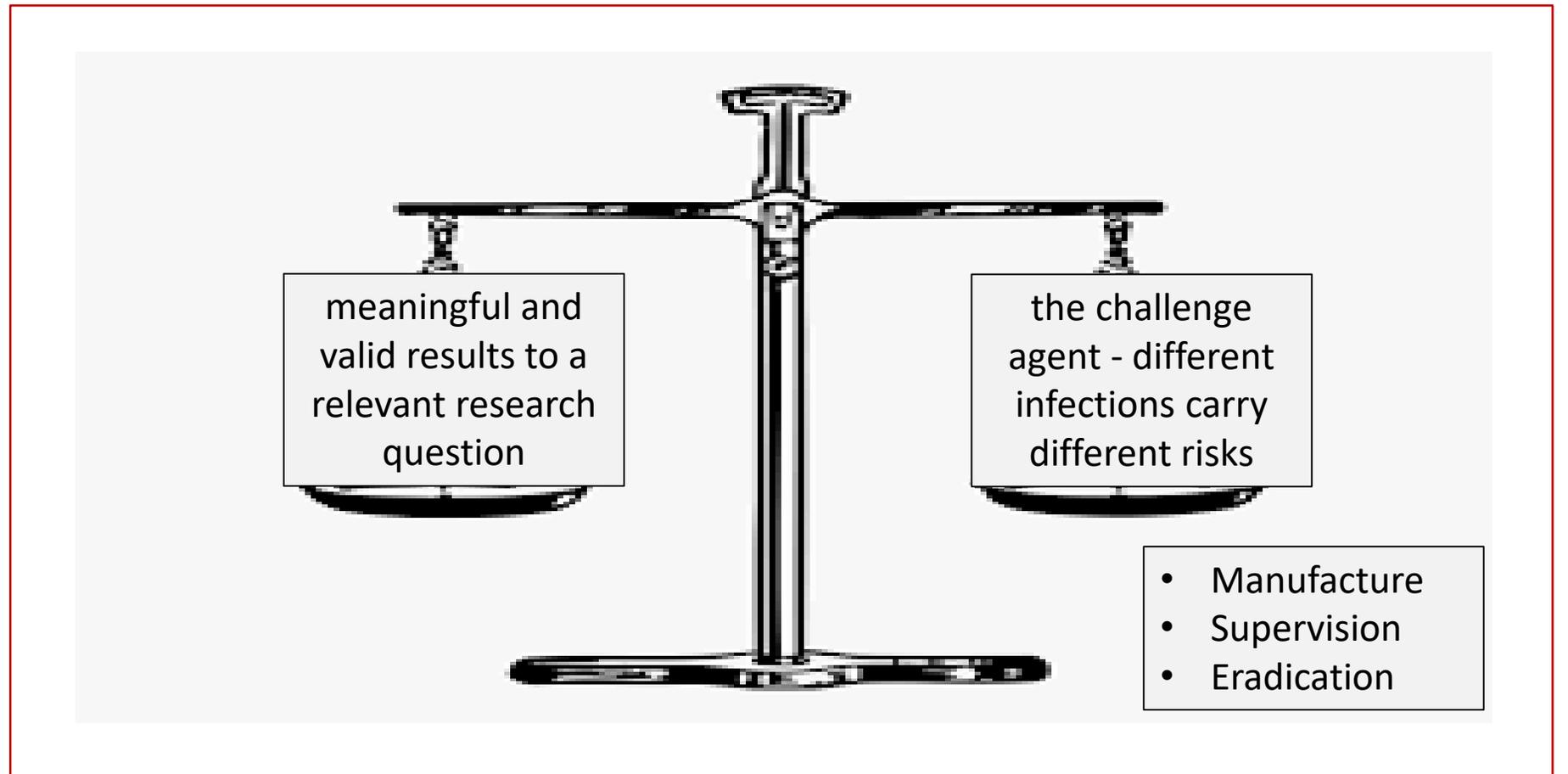
Will participants be selected and recruited fairly?

This should include

- confirmation of inclusion/exclusion criteria from health care practitioner (e.g. GP).
- a health assessment conducted by a qualified physician.
- consideration of psychological testing.
- identification of a fixed address and access to mobile communications.

Particular issues in H.I.C.S.

Is there fair balance of benefits and harms (i/iv)?



Particular issues in H.I.C.S.

Is there fair balance of benefits and harms (ii/iv)?

Contacts and environmental issues

- These will depend on the infecting agent, the likelihood of spread, its consequences and whether the infection is prevalent in the community.
- Broader contacts: assessment is needed as to whether the organism might get into groundwater and hence into water supplies or into animals, particularly those in the food chain or infect food handlers.

Particular issues in H.I.C.S.

Is there fair balance of benefits and harms (iii/iv)?

Arrangements might include:-

- Social and household restrictions.
- Isolation for a period of time.
- Arranging short term admissions.
- Informing families or household contacts what to look for, whom to contact with 24-hour cover telephone line as appropriate.

Particular issues in H.I.C.S.

Is there fair balance of benefits and harms (iv/iv)?



Particular issues in H.I.C.S.

Will fair informed consent be sought?

Some key issues MUST be understood

- they will be infected with
- any requirements
- what symptoms
- what

Some ideas how to get these across

<http://www.reviewingresearch.com/consent/#key>

before eradication treatment
(if limited).
by default, others may need to be contacted

Particular issues in H.I.C.S.

Will there be fair payments and compensation for injury?

Payment

- payment shouldn't be related to any putative risk.
- local pay rates must be considered.

Recompense

- such arrangements must be in place. The participants will almost certainly display symptoms and it must be clear what the insurance policy will cover.

Particular issues in H.I.C.S.

Will appropriate care after research be
in place?

Eradication must be completed.

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From Oxford UK, best wishes, good luck and
thank you for listening!
(If you have been!)

